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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,486	12/13/2001	Friedhelm Eisenbeiss	MERCK 2334	1799
23599	7590	06/04/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			OLSEN, KAJ K	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,486

Applicant(s)

EISENBEISS ET AL.

Examiner

Kaj K Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-19 is/are pending in the application.
4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 7-17 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claim 18 and 19 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The special technical feature of new claims 7-17 is the microanalytical system where the channels are not coated with adhesive. This is the same special technical feature of originally examined claims 1-6. The special technical feature of claims 18 and 19 are the analytical system having an electrode constructed of chromium oxide and a noble metal.
2. Since applicant has received an action on the merits for the special technical feature of claims 7-17 (originally claims 1-6), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18 and 19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 7-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. There does not appear to be prior support for the limitation requiring the joined components to be in a parallel relation at the point of joining. Applicant urges that p. 15, lines 14-19, fig. 2-4, and the applicant's use of optical markers are evidence for this new limitation. The examiner disagrees. All p. 15, lines 14-19 and the optical markers evidence is that the components must be aligned at some point in time. First, alignment is not the same thing as maintaining the components in parallel at the time of joining. In fact, fig. c) in applicant's arguments evidences that two plates can be maintained in alignment, but not joined in parallel as is now being claimed. Second, even if the alignment means (i.e. optical markers) is construed as requiring the components to be in parallel (although there does not appear to be anything in the record requiring such a construing), all the alignment means indicates is that the component must be in parallel at some point that is not necessarily the joining moment. With respect to fig. 2 and 3, all these figures show is the two components first separated from each other and then joined. There is nothing inherent in these figures that leads one to necessarily have the joining process be in parallel. Why couldn't the components of fig. 2a and 3a be brought together like the applicant shown in fig. c) of the applicant's arguments? Based on these figures, it might have been obvious to join the components in parallel, but the criteria for new matter is not what would have been obvious, but what did the applicant originally convey his/her invention to be. With respect to fig. 4, this figure appears to just show the use of an optical marker. As discussed above, this just demonstrates alignment.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. With respect to claim 14, the use of the "or" at the end of the claim is confusing. Is applicant specifying the presence of one element of the five or is applicant specifying the presence of the first three elements and either the fourth or fifth element of the claim? For the purpose of examination, the examiner is interpreting it as the former, but clarification is requested.
9. With respect to claim 15, the use of "unstructured" is confusing. It would appear this is referring to a portion of a component that lacks a microstructure, but "unstructured" is not the opposite of "lacking a microstructure". Why would the surface of component 2 in fig. 2 be any less "unstructured" than the microstructure itself?
10. With respect to claim 16, it is unclear how one would reasonably construe "generally the same time".

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 7, 10, 13-15, and 17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Besemer et al (USP 6,140,044). Besemer is being cited and relied on for the first time with this office action. Its use here was necessitated by applicant's new claims.

13. Besemer discloses a process for producing an analytical system that comprises providing at least two plastic components where one of the components has at least one channel (551, 561), wetting at least one of the components with adhesive, aligning the components, pressing and joining the components together, and curing the adhesive. See fig. 5a and 5b; col. 5, line 41 through col. 6, line 3; col. 8, lines 16-46; and col. 12, lines 32-48. With respect to channel being "microstructured", it would appear that any number of the various elements of Besemer, including the channels, would read on the term "microstructured" giving the claim language its broadest reasonable interpretation. With respect to the joining being performed in parallel, Besemer teaches the use of alignment pins and holes (col. 8, lines 36-39). The use of pins and holes would ensure that the two components are being brought together in parallel. With respect to the absence of adhesive in the channel, it would now appear from the applicant's discussion that parallel joining provides that desired property. In addition, Besemer teaches only placing the adhesive in a trough, and explicitly teaches that care must be taken to ensure the adhesive does not seep into the microstructures (col. 12, lines 32-48).

14. With respect to the thickness of adhesive applied, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize 0.5-10 microns. Using too little adhesive and the adhesion strength would be insufficient. Too much adhesive would cause undesirable seepage of the adhesive into the microstructures (col. 12, lines 32-48).

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Finding the appropriate balance between these competing conditions requires only routine skill in the art.

15. With respect to applying the adhesive to an unstructured region, the adhesive is being applied away from the channels or cavities. That would appear to read on applicant's "unstructured region" giving the claim language its broadest reasonable interpretation.

Alternatively, even if the trough of Besemer were not construed as being "unstructured" (see 112 rejection), one possessing ordinary skill in the art would recognize that the adhesive could be applied at any number of locations away from the structured elements of the invention, including any number of surfaces that are "unstructured".

16. Claims 10 and 11 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bentsen et al (USP 6,375,871 B1) (with or without WO '693 and/or WO '535) or Chow et al (USP 5,989,402). Chow is being cited and relied on for the first time with this office action. Its use was necessitated by the amended claims.

17. Bentsen (or Bentsen in view of WO '693 and/or WO '535) was utilized before to reject the product-by-process claims (i.e. claims 4 and 5). New claims 10 and 11 are similarly product-by-process claims as they are likewise rejection by this teaching or combination of teachings. Chow is an alternate analytical system having electrodes that are embedded between to plastic components. See fig. 3a and 3b; col. 5, line 42 through col. 6, line 5; and col. 12, lines 25-56. Because the product of the claim is identical to the invention of Chow, the process from which it was made is the same as or obvious over the process utilized by Chow (see *In re Thorpe*, 777 F.2d 695, 698).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 7, 8, 13-15, and 17 (and claims 10 or 11 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen or Chow in view of Besemer.

20. Bentsen and Chow individually disclose all the limitations of the claimed analytical system, but do not explicitly set forth a process where the components are joined in parallel. However, Besemer showed one process where the various components of an analytical system can be joined together (see rejection above). Said process provided a means for joining two components together that ensured their alignment. In addition, said process provides a bonding means that ensures that the various structures of the analytical system are not coated or clogged with adhesive. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the process of Besemer for the analytical system of either Bentsen or Chow in order to ensure appropriate alignment of the various components and to ensure that adhesive has not been allowed to seep into the microstructural elements of the analytical system.

21. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Besemer in view of Harden et al (USP 6,406,583 B1).

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22. Claims 9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Benstsen or Chow in view of Besemer as applied to claim 7 above, and further in view of Harden.

23. Besemer set forth all the limitations of the claim, and further specified that optical marker can be utilized for the aligning process (col. 6, lines 4-15). However, Besemer never specified the composition of its alignment markers 145. Hence, it cannot be determined if these markers have been sputtered on. Harden teaches the use of metallic markers and further teaches that the use of sputtering to arrive at metallic patterns on the substrates (which presumably includes the markers) is old in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Harden for the process of Besemer because the use of conventional means for depositing markers requires only routine skill in the art.

24. With respect to claim 16 and the electrode and marker being applied "generally" at the same time, this wouldn't appear to read free of separate steps of applying electrode material and marker. However, one possessing ordinary skill in the art would have recognized that applying the marker and electrode at the same time would have saved one a separate deposition step.

25. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen alone, Bentsen and WO '693 (with or without WO '535), or Bentsen in view of Besemer in further view of WO 98/09161 A1 (hereafter "WO '161").

26. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Chow alone or Chow in view of Besemer in further view of Bentsen.

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27. With respect to Bentsen, the reference or references set forth all the limitations of the claim, and Bentsen further disclosed an adhesion layer of chromium oxide (paragraph bridging col. 13 and 14). Bentsen did not explicitly disclose the use of a noble metal for the electrode (Bentsen utilized copper). WO '161 teaches that appropriate choices for electrode materials include a number of inert materials including noble metals platinum and gold (p. 6, lines 25-31). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '161 for the product of Bentsen (with or without the teachings of WO '693, WO '535, or Besemer) in order to ensure the electrode materials are appropriately inert.

28. With respect to Chow, Chow already discloses the use of noble metal electrodes (col. 13, line 50 through col. 14, line 11), but did not explicitly disclose the use of chromium oxide as an adhesion layer. However, the Bentsen already disclosed the utility of chromium oxide as an adhesion layer (col. 14, lines 7-12). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Bentsen for the adhesion layer for Chow because the substitution of one known adhesion means for another requires only routine skill in the art.

Response to Arguments

29. Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection required by the new claims 7-17. However, because the rejection of the product by process claims is still being maintained with respect to Bentsen alone and Bentsen in view of WO '693, WO '535, applicant urges, both in arguments and via affidavit,

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that because Bentsen does not keep the components in parallel during the joining process, the channels become coated with adhesive. That may be true, but the rejection was based on the fact that the prior art already recognized that care must be taken in order to avoid glue in the channels. See the previous rejection. If the prior art utilized a different means (i.e. patterned gluing) to ensure that adhesive didn't get into the channels, then that prior art would have arrived at the claimed product irrespective of the process utilized. That was the basis for the rejection. With respect to the combination of Bentsen and WO '161, applicant appears to be urging that neither reference anticipated the claims. The examiner agrees, but the rejection was based on the obviousness of the combination of references. Applicant urges that copper was the preferred material of Bentsen. That may be the case, but why are other metals (especially metals already in the microfluidic art) unobvious?

Conclusion

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 6:30 A.M. to 4:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a stylized flourish extending to the right.

Kaj K. Olsen Ph.D.

Primary Examiner

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May 31, 2004